GR 1804

RPR File No. EX93015-US

#19
G.R.
01/02/97

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Perricaudet et al.

Serial No.: 08/397,225 Group Art Unit: 1804

International Filing Date: July 8, 1994 Examiner: S. Ziska

For: Defective Adenovirus Vectors And Use Thereof In Gene Therapy

To: Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING (37 CFR § 1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Paula L. Dickey
(Type or print name of person mailing paper)

Date: Nov 26, 1997

Paula L. Dickey
(Signature of person mailing paper)

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT BEFORE MAILING DATE OF EITHER A FINAL ACTION OR NOTICE OF ALLOWANCE (37 CFR 1.97(c))

The information disclosure statement transmitted herewith is being filed after three months of the filing date of this national application or the date of entry of the national stage as set forth in §1.491 in an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last but before the mailing date of either: (1) a final action under §1.113 or (2) a notice of allowance under §1.311, whichever occurs first.

Please charge Deposit Account No. 18-1982 in the amount of $240.00 to cover the cost of the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under §1.97(c). Any deficiency or overpayment should be charged or credited to Deposit Account No. 18-1982. A **triplicate** of this sheet is enclosed.

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Respectfully submitted,

Dated: 11/25/97

Paul F. Fehlner, Ph.D.
Attorney for Applicants
Registration No. 35,135

Rhône-Poulenc Rorer Inc.
P.O. Box 5093, Mail Stop 3C43
Collegeville, PA 19426-0997
Telephone: (610) 454-3839
Facsimile: (610) 454-3808

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Paula L. Dickey
(Type or print name of person mailing paper)

Date: Nov 26, 1997

Paula L. Dickey
(Signature of person mailing paper)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. §§ 1.97 AND 1.98

Dear Sir:

Applicants submit herewith a list of patents and publications, and copies thereof as required by 37 CFR § 1.98, which Applicants believe the Examiner may consider to be material to the patentability of claims of this application and for which there may be a duty to disclose in accordance with 37 CFR § 1.56. Copies of pending US applications are not provided. Copies of the cited International Patent Publications are provided.

While the patents and publications disclosed herein may be "material" within the meaning of 37 CFR § 1.56, Applicants' inclusion thereof in this Statement is not intended to constitute an admission that any such patent or publication is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR § 1.97 (g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that the information cited is material to patentability as defined in 37 CFR § 1.56(b).

Applicants believe that the claims in the present application are patently distinguishable over the patents and publications listed on the attached Information Disclosure Citation Form.

The Examiner is requested to review the Information Disclosure Statement and initial the PTO Form 1449 to indicate review of the cited references. Applicants further request that the Examiner return the initialed Information Disclosure Citation form submitted June 12, 1995 (copy of form and Information Disclosure Statement enclosed).

The attached Information Disclosure Citation Form cites co-pending cases in the United States Patent Office, Serial No. 08/417,674, filed November 20, 1984; Serial No. 111,947, filed September 27, 1991; and Serial No. 08/553,317, filed May 6, 1994. Applicants hereby inform the Examiner that Serail Nos. 08/417,674, 111,947, and 08/553,317 concerns similar subject matter to the instant application. The 08/553,317 application is the national application based on WO 94/26914, a copy of which is provided.

Applicants note that International Patent Publication WO 94/28152 designates the US. This publication discloses and claims E4 and E2 deleted adenoviruses.

The information disclosure statement transmitted herewith is being filed after three months of the filing date of this national application or the date of entry of the national stage as set forth in §1.491 in an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last but before the mailing date of either: (1) a final action under §1.113 or (2) a notice of allowance under §1.311, whichever occurs first. Pursuant to 37 CFR §1.97(c), this statement requires a fee as set forth in the Transmittal paper to which this Information Disclosure Statement is attached.

Respectfully submitted,

Paul F. Fehlner, Ph.D.
Attorney for Applicants
Registration No. 35,135

Dated: 11/25/97

Rhône-Poulenc Rorer Inc.
P.O. Box 5093, 3C43
500 Arcola Road
Collegeville, PA 19426-0997
Telephone: (610) 454-3839
Telecopy: (610) 454-3808

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	Perricaudet, et al.	Group Art Unit:
Serial No.:	08/397,225	Examiner:
Filed:	28 March 1995	

For: DEFECTIVE ADENOVIRUS VECTORS AND USE THEREOF IN GENE THERAPY

To: The Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Julie K. Smith
Type or print name of person mailing paper

Date: 12 June 1995

JKS
Signature of person mailing paper

INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR §§ 1.97 AND 1.98

Dear Sir:

Applicants submit herewith a list of patents and publications which Applicants believe the Examiner may consider to be material to the patentability of claims of this application and which there may be a duty to disclose in accordance with 37 CFR § 1.56. Each listed reference was cited in the International Search Report, and copies were sent to the USPTO as an Designated Office. Accordingly, no copies are included herewith.

While the patents and publications disclosed herein may be "material" within the meaning of 37 CFR § 1.56, Applicants' inclusion thereof in this Statement is not intended to constitute an admission that any such patent or publication is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR § 1.97 (g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search

has been made or that the information cited is material to patentability as defined in 37 CFR § 1.56(b).

Applicants believe that the claims in the present application are patently distinguishable over the patents and publications listed on the attached Information Disclosure Citation Form.

This Information Disclosure Statement is being filed before the first Office Action on the merits of this application and accordingly, pursuant to 37 CFR § 1.97 (b)(3), this statement requires neither a fee nor a certification.

Rhône-Poulenc Rorer Inc.
500 Arcola Road, 3C43
Collegeville, PA 19426-0107
Telephone: (610) 454-3839
Facsimile: (610) 454-3808

Dated: 12 June 1995

Respectfully submitted,

Julie K. Smith
Agent for Applicants
Registration No: 38,619

hydrophilic polymer incorporating the nucleic acid. The nucleic acid may be any nucleic acid, including antisense DNA or RNA. The nucleic acid may encode hormones, enzymes, receptors or drugs of interest. The nucleic acid is selected based upon the desired therapeutic outcome. For example, in the treatment of ischemic diseases, one would select a DNA encoding an angiogenic protein. The nucleic acid may be carried by a microdelivery vehicle such as cationic liposomes and **adenoviral** vectors. DNA encoding different proteins may be used separately or simultaneously.

7. 5,646,034, Jul. 8, 1997, Increasing rAAV titer; Michael Mamounas, et al., 435/325, 91.4, 172.3, 320.1 :IMAGE AVAILABLE:

US PAT NO: 5,646,034 :IMAGE AVAILABLE: L9: 7 of 13

ABSTRACT:
Methods, kits and compositions for increasing the titer of rAAV vectors are provided.

8. 5,616,559, Apr. 1, 1997, Papillomavirus E2 trans-activation repressors; Elliot J. Androphy, et al., 514/12; 530/350 :IMAGE AVAILABLE:

US PAT NO: 5,616,559 :IMAGE AVAILABLE: L9: 8 of 13

ABSTRACT:
This invention relates to E2 trans-activation repressors which interfere with normal functioning of the native full-length E2 transcriptional activation protein of the papillomavirus. Native full-length E2 trans-activation protein activates transcription of papillomavirus only through binding to DNA, and it binds to DNA only in the form of a pre-formed homodimer--a pair of identical polypeptide subunits held together by non-covalent interactions. The E2 trans-activation repressors of this invention are proteins, polypeptides or other molecules that dimerize with full-length native E2 polypeptides to form inactive heterodimers, thus interfering with the formation of active homodimers comprising full-length native E2 polypeptides, thereby repressing papillomavirus transcription and replication. The E2 trans-activation repressors of this invention are advantageously used in the treatment of papillomavirus infections and their associated diseases.

9. 5,595,884, Jan. 21, 1997, Papillomavirus E2 transactivation repressor proteins and DNA; Elliot J. Androphy, et al., 435/69.1, 252.31, 252.33, 252.34, 252.35, 254.21, 320.1, 348, 354, 358, 363, 364, 365, 366; 514/2; 530/350, 826; 536/23.72; 930/220 :IMAGE AVAILABLE:

US PAT NO: 5,595,884 :IMAGE AVAILABLE: L9: 9 of 13

ABSTRACT:

This invention relates to E2 trans-activation repressors which interfere with normal functioning of the native full-length E2 transcriptional activation protein of the papillomavirus. This invention also relates to DNA sequences and recombinant DNA molecules encoding such repressors, unicellular hosts transformed with such DNA molecules, and processes for producing and using such repressors. Native full-length E2 trans-activation protein activates transcription of papillomavirus only through binding to DNA, and it binds to DNA only in the form of a pre-formed homodimer--a pair of identical polypeptide subunits held together by non-covalent interactions. The E2 trans-activation repressors of this invention are proteins, polypeptides or other molecules that dimerize with full-length native E2 polypeptides to form inactive heterodimers, thus interfering with the formation of active homodimers comprising full-length native E2 polypeptides, thereby repressing papillomavirus transcription and replication. The E2 trans-activation repressors of this invention are advantageously used in the treatment of papillomavirus infections and their associated diseases.

10. 5,591,439, Jan. 7, 1997, Recombinant cytomegalovi[redacted] vaccine; Stanley A. Plotkin, et al., 424/199.1, 230.1, 233.1; 435/5, 69.3, 172.3, 235.1; 536/23.1, 23.72 :IMAGE AVAILABLE:

US PAT NO: 5,591,439 :IMAGE AVAILABLE: L9: 10 of 13

ABSTRACT:
The present invention provides a non-**defective adenovirus** **recombinant** expression system for the expression of the HCMV gB subunit and for the expression of non-structural immediate-early exon 4 proteins, said recombinant HCMV-expressing **adenovirus** being useful as a vaccine.

11. 5,571,712, Nov. 5, 1996, Non-infectious, replication defective, immunogenic HIV retrovirus-like particles produced from a recombinant HIV genome devoid of long terminal repeats; Joel Haynes, et al., 435/364; 424/188.1, 208.1; 435/69.3, 172.3, 320.1, 365; 536/23.72 :IMAGE AVAILABLE:

US PAT NO: 5,571,712 :IMAGE AVAILABLE: L9: 11 of 13

ABSTRACT:
This invention is directed towards nucleic acid molecules capable of producing human immunodeficiency virus (HIV) retrovirus-like particles, which are non-infectious, replication **defective**, and immunogenic. **Recombinant** HIV genomes were generated that are devoid of long terminal repeats (LTRs) but contain a heterologous, inducible metallothionein promoter. Additional modifications have been made to the primer binding site, pol, vif, and env coding regions. Upon transfection into a suitable host these DNA molecules are capable of producing HIV retrovirus-like particles that lack genomic RNA. These non-infectious particles will provide suitable antigens for HIV diagnostic assays and immunogenic preparations.

12. 5,552,143, Sep. 3, 1996, Recombinant cytomegalovirus vaccine; Stanley A. Plotkin, et al., 424/199.1, 186.1, 230.1, 233.1, 278.1; 435/69.1, 69.3, 172.3, 235.1; 536/23.1, 23.72 :IMAGE AVAILABLE:

US PAT NO: 5,552,143 :IMAGE AVAILABLE: L9: 12 of 13

ABSTRACT:
The present invention provides a non-**defective adenovirus** **recombinant** expression system for the expression of the HCMV gB subunit, an immunogenic fragment of the gB subunit, and for the expression of non-structural immediate-early exon 4 proteins, said recombinant HCMV-expressing **adenovirus** being useful as a vaccine.

13. 5,219,990, Jun. 15, 1993, Papillomavirus E2 trans-activation repressors; Elliot J. Androphy, et al., 530/350, 300, 324, 826; 930/220 :IMAGE AVAILABLE:

US PAT NO: 5,219,990 :IMAGE AVAILABLE: L9: 13 of 13

ABSTRACT:
This invention relates to E2 trans-activation repressors which interfere with normal functioning of the native full-length E2 transcriptional activation protein of the papillomavirus. Native full-length E2 trans-activation protein activates transcription of papillomavirus only through binding to DNA, and it binds to DNA only in the form of a pre-formed homodimer--a pair of identical polypeptide subunits held together by non-covalent interactions. The E2 trans-activation repressors of this invention are proteins, polypeptides or other molecules that dimerize with full-length native E2 polypeptides to form inactive heterodimers, thus interfering with the formation of active homodimers

comprising full-length native E2 polypeptides, thereby repressing papillomavirus transcription and replication. The E2 trans-activation repressors of this invention are advantageously used in the treatment of papillomavirus infections and their associated diseases.